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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,952	04/16/2004	Inder Raj S. Makin	END5311USNP	8216

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT	PAPER NUMBER
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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,952	Applicant(s) MAKIN ET AL.	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14, 16, 17, 19, 20, 22, 23, 25, 26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14, 16, 17, 19, 20, 22, 23, 25, 26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/8/2007; 11/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 discloses that the third ultrasound transducer has a plurality of ultrasound transducer elements, which does not further limit claim 1, which discloses that the third ultrasound transducer has a plurality of transducer elements.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 discloses that the third ultrasound transducer has only one ultrasound transducer element, which conflicts with the base claim 1 which discloses that the third ultrasound transducer has a plurality of transducer elements. This renders the claim to be indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-6, 9, 16-17, 19-20 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujio et al. (US Patent No. 5,471,988).

With regards to claims 1-6, 9, 16-17, and 19-20, Fujio et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, having a distal end, and having: a) a first ultrasound transducer (479) disposed proximate the distal end and having a substantially-fully-cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis (see Figures 64 and 67; column 53, lines 36-53); b) a second ultrasound transducer (479') having a substantially-fully cylindrical ultrasound-emitting outer-exposed surface which is substantially coaxially aligned with, and outwardly-facing from the longitudinal axis (see Figures 64 and 67; column 53, lines 36-53); and a third ultrasound transducer (478) disposed longitudinally between the first and second ultrasound transducers and having a plurality of planar transducer elements arranged to provide the third ultrasound transducer with an ultrasound-emitting outer exposed surface which is substantially-entirely planar (see Figures 64-65 and 67; column 53, lines 36-53). The first ultrasound transducer (479) is disposed at the distal end, and the third ultrasound transducer (478) is disposed proximate the first (479) and second (479') ultrasound transducers (see Figures 64 and 67). The ultrasound-emitting outer-exposed surface of the first (479), second (479') and third ultrasound transducer

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(478) in its entirety have a substantially cylindrically/spherically focused shape (see Figures 64 and 67). The first and second ultrasound transducer (479,479') are ultrasound-medical treatment-only ultrasound transducers (column 53, lines 36-43). Each of the first, second and third ultrasound transducers have a plurality of transducer elements (see Figures 64 and 67, column 53, lines 36-53). The transducer assembly includes at least a concave surface portion (see Figure 65). The third ultrasound transducer is an ultrasound-medical-imaging only ultrasound transducer (column 53, lines 36-53).

With regards to claims 28-30, Fujio et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, having a distal end, and having two ultrasound transducers, wherein one of the ultrasound transducers has a substantially fully cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis, and wherein an other of the ultrasound transducers is disposed longitudinally proximal or distal to the one ultrasound transducer and has a plurality of planar transducer elements arranged to provide the other ultrasound transducer with an ultrasound-emitting outer exposed surface which is substantially-entirely planar or includes at least a concave surface portion (see Figures 27 and 29; column 30, line 13-column 32, line 52). The one ultrasound transducer is disposed proximate the distal end, and wherein the other ultrasound transducer is disposed proximate, and proximal to, the one ultrasound transducer (see Figures 27 and 29). The one and other ultrasound transducers are different types of medical-treatment only type and medical

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imaging only type transducers (column 30, line 13-column 32, line 52). Each of the two ultrasound transducers can have a plurality of planar transducer elements (see Figures 27 and 29, column 30, line 13-column 32, line 52).

6. Claims 31-32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz (US Patent No. 6,770,070).

Balbierz discloses an ultrasound medical system comprising a transducer assembly having a longitudinal axis, having a distal end, and having: a) an exposed first RF (radio-frequency) medical-treatment electrode (18) aligned substantially coaxially with the longitudinal axis; and an exposed ultrasound medical transducer (22) disposed longitudinally proximal or distal to the first RF medical treatment electrode (See Figure 20; column 12, lines 39-67; column 17, line 24-column 18, line 40) The first RF medical-treatment electrode is disposed proximate the distal end, and the ultrasound medical transducer is disposed proximate, and longitudinally proximal to, the first RF medical-treatment electrode (see Figure 20). The first RF medical-treatment electrode is disposed at the distal end and tapers to a tissue-penetrating edge (column 14, lines 47-65).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio et al. as applied to claim 1 above, and further in view of Makin et al. (US Pub No. 2003/0018266).

As discussed above, Fujio et al. meet the limitations of claim 1. However, they do not specifically disclose that the third ultrasound transducer is an ultrasound-medical-treatment-and-imaging ultrasound transducer. Makin et al. disclose an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality of ultrasound transducers. They disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer which allows monitoring during treatment (pg. 1, paragraph [0004]; pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the third transducer in the system of Fujio et al. to be an ultrasound-medical-treatment-and-imaging ultrasound transducer, as taught by Makin et al., in order to monitor the ultrasound treatment (pg. 1, paragraph [0004]).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio et al. as applied to claim 1.

As discussed above, Fujio et al. meet the limitations of claim 1. Further, Fujio et al. disclose an embodiment of their invention, in which they disclose that an ultrasound treatment transducer (i.e. the first and second transducers in the embodiment discussed above for instant claim 1) may be a single ultrasonic transducer or a plurality of ultrasonic transducers (column 30, lines 56-67). At the time of the invention, it would

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have been obvious to one of ordinary skill in the art to substitute at least one of the first, second, and third ultrasound transducers to have only one ultrasound transducer element, as taught by Fujio et al., as Fujio teaches that a plurality of transducers and a single transducer are interchangeable and can serve the same purpose (column 30, lines 56-67).

10. Claims 10-11, 13-14, 22-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio et al. (US Patent No. 5,471,988) in view of Makin et al.

With regards to claims 10-11 and 13-14, Fujio et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, and having a first (479), second (479') and third (478) ultrasound transducers each having a plurality of transducer elements arranged to provide each of the first, second, and third ultrasound transducers with an ultrasound-emitting outer-exposed surface which includes at least a concave surface portion, wherein the first and second ultrasound transducers are ultrasound-medical-treatment-only ultrasound transducers, and wherein the third ultrasound transducer is disposed longitudinally between the first and second ultrasound transducers (see Figures 64-65 and 67; column 53, lines 36-53). The ultrasound transducer assembly has a distal end, wherein the first ultrasound transducer is disposed proximate the distal end, and wherein the third ultrasound transducer is disposed proximate the first and second ultrasound transducers (see Figures 64 and 67; column 53, lines 36-53). The ultrasound emitting outer-exposed surfaces of the first, second and third ultrasound transducers together in their entirety have a substantially-cylindrically/spherically focused shape (see Figures 64 and 67). As

can be seen in Figure 65, the first and second transducers (479, 479') are concave, and the third transducer (478) is planar. Fujio et al. do not specifically disclose that the plurality of transducer elements of the first and second transducers are planar, however, they do disclose for a separate embodiment that an ultrasonic transducer is not limited to a concave one, but may be constructed with planar transducers if they are constructed in a phase-array arrangement so that phase is shifted to focus the ultrasonic beam (column 30, lines 56-67). At the time of the invention, it would have been obvious to modify the system of Fujio et al. to have the plurality of transducer elements be planar, as Fujio et al. teaches that planar transducers may be employed to serve the same purpose as concave transducers.

However, Fujio et al. do not specifically disclose that the third ultrasound transducer is an ultrasound-medical-treatment-and-imaging ultrasound transducer.

Makin et al. disclose an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality of ultrasound transducers. They disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer which allows monitoring during treatment (pg. 1, paragraph [0004]; pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the third transducer in the system of Fujio et al. to be an ultrasound-medical-treatment-and-imaging ultrasound transducer, as taught by Makin et al., in order to monitor the ultrasound treatment (pg. 1, paragraph [0004]).

With regards to claims 22-23 and 25-26, Fujio et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, and having first (479), second (479') and third ultrasound transducers each having a plurality of transducer elements arranged to provide each of the first, second and third ultrasound transducers with an ultrasound-emitting outer exposed surface which includes at least a concave surface portion, wherein the first and second ultrasound transducers are ultrasound medical treatment transducers, and wherein the third ultrasound transducer is disposed longitudinally between the first and second ultrasound transducers (see Figures 64-65 and 67; column 53, lines 36-53). The ultrasound transducer assembly has a distal end, wherein the first ultrasound transducer is disposed proximate the distal end, and wherein the third ultrasound transducer is disposed proximate the first and second ultrasound transducers (see Figures 64 and 67; column 53, lines 36-53). The ultrasound-emitting outer exposed surfaces of the first, second, and third ultrasound transducers together in their entirety have a substantially-cylindrically/spherically focused shape (see Figures 64 and 67). As can be seen in Figure 65, the first and second transducers (479, 479') are concave, and the third transducer (478) is planar. Fujio et al. do not specifically disclose that the plurality of transducer elements of the first and second transducers are planar, however, they do disclose for a separate embodiment that an ultrasonic transducer is not limited to a concave one, but may be constructed with planar transducers if they are constructed in a phase-array arrangement so that phase is shifted to focus the ultrasonic beam (column 30, lines 56-67). At the time of the invention, it would have

been obvious to modify the system of Fujio et al. to have the plurality of transducer elements be planar, as Fujio et al. teaches that planar transducers may be employed to serve the same purpose as concave transducers.

However, they do not disclose that the first and second ultrasound transducers are ultrasound-medical-treatment-and-imaging ultrasound transducers, and the third ultrasound transducer is an ultrasound-medical-treatment only ultrasound transducer. Makin et al. disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer and that at least one of the transducers is an ultrasound medical treatment transducer (pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Fujio et al. to have the first and second ultrasound transducers be ultrasound medical treatment and imaging ultrasound transducers and have the third transducer be an ultrasound-medical-treatment only transducer, as taught by Makin et al., in order to successfully apply and monitor ultrasound treatment, as taught by Makin et al. (pg. 1, paragraph [0004]).

11. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz as applied to claim 31 above, and further in view of Manna et al. (US Patent No. 6,902,536).

As discussed above, the above combined references meet the limitations of claim 31. Further, Balbierz discloses that their system includes an exposed second RF medical-treatment electrode (18') (See Figure 20, column 16, lines 7-25; column 17, lines 51-60). However, they do not specifically disclose that the ultrasound medical

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transducer is disposed longitudinally between the first and second RF medical treatment electrodes. Manna et al. disclose an ultrasonic medical treatment device pursuant to the present invention comprising a casing, an elongate probe, a transducer assembly, a sheath and at least one electrode member (column 3, lines 29-57). Manna et al. disclose that their system can also include a second RF medical-treatment electrode (34), wherein the ultrasound medical transducer(40, 62) is disposed longitudinally between the first and second RF medical treatment electrodes (column 7, lines 4-36 and lines 28-42). See Figure 3B. Manna et al. disclose that this configuration provides physicians with designs that can be used without losing dexterity or visibility of the operation site, and allows for bipolar cauterization without energizing the tool tip itself (column 7, lines 58-63). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Balbierz to have the ultrasound medical transducer be disposed longitudinally between the first and second RF medical treatment electrodes, as taught by Manna et al., in order to not lose dexterity or visibility of the operation site and allow for bipolar cauterization without energizing the tool tip itself (column 7, lines 58-63).

Response to Arguments

12. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768